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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/787,417	02/27/2004	Chien-Hsuan Han	7483/88058	4537

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FITCH, EVEN, TABIN & FLANNERY
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WASHINGTON, DC 20036

EXAMINER

MAEWALL, SNIGDHA

ART UNIT	PAPER NUMBER
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1615

MAIL DATE	DELIVERY MODE
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05/18/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/787,417

Applicant(s)

HAN ET AL.

Examiner

Snigdha Maewall

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-33 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-33 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>06/09/04 and 08/31/004</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Summary

1. Receipt of IDS filed on 06/09/2004 and 08/31/2004 is acknowledged.

Claims 1-33 are pending in this application and claims 1-33 will be prosecuted on the merits.

Double Patenting

2. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

3. Claims 1, 3-6, 16-22 and 24 -33 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-31 of US Patent No. 7,094,427 B2. Although the conflicting claims are not identical, they

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are not patentably distinct from each other because similar subject matter has been claimed. Claims 1, 3-6, 16-22 and 24 -33 of instant application 10787417 are drawn to a pharmaceutical dosage form having an immediate release component and a controlled release component, wherein the immediate release component comprises a particular ratio (1:1 to about 1:50) of Carbidopa to Levodopa and release profile for Levodopa and wherein the controlled release component also comprises a particular ratio (1:1 to about 1:50) of Carbidopa to Levodopa and release profile for Levodopa. Claims 1-31 of the US Patent No. 7,094,427 B2 are also drawn to a pharmaceutical dosage form having an immediate release component and a controlled release component of Carbidopa and Levodopa with particular ratios and release profiles. The only difference observed between the patented claims and the instant application are the claimed component of Carbidopa and Levodopa with particular ratios and release profiles which are deemed to be obvious parameters manipulated by an artisan.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 1-33 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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Claims 1 and 22 recite the limitation "at least about". The term is indefinite as it does not provide the specific amount limitations of the claim.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 1, 3-6, 16-22 and 24 -33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Conte et al. (US Patent No. 6,294,200).

Conte et al. teaches a pharmaceutical tablet capable of delivering active substance(s) according to a predetermined release profile, whereby the tablet is characterized as having (a) a core consisting of three layers, in which 1) the upper layer contains an active substance, which is immediately released; 2) an intermediate layer which determines the time interval between the release of the active substance contained in the upper layer (1) and the lower layer (3); and 3) a lower layer formulated to have release of the active substance with prefixed kinetics and controlled release of the active substance and (b) a coating applied on the lower and lateral surface of the core. Conte et al. teach that various active substances may be employed that include, antiparkinson drugs such as Levodopa, Carbidopa and Benserazide (column 2, line 13 and column 8, line 41).

Example 7 at columns 19-21 exemplifies tablets containing a mixture of anti-Parkinson drugs, Carbidopa and Levodopa having a release profile as shown in Table VII. In order to estimate the release characteristics of the tablets the equipment 2, paddle (described in USP XXII) is used operating at 100 rpm and using deionized water at 37°C as the dissolution fluid. In the preparation of the first granulate for Layer 1, 30 mgs of Carbidopa and 30 mg of Levodopa are used. A second granulate for preparing Layer 3 contains 25 mg of Carbidopa and 100 mg of Levodopa. A coating is also included. The release profiles of Table VII demonstrate the Time (in mins), the % Carbidopa released and the % Levodopa released. For example, in 15 mins. 53.9% of Carbidopa was released and 21.0% of Levodopa was released. After 30 mins. 55.4% of Carbidopa and 23.0% Levodopa was released and so forth as seen in the Table.

It would have been obvious to the one of ordinary skilled in the art at the time the invention was made to optimize the release profile of Conte et al. because Conte et al. teaches a release profile which is in close proximity with the release characteristics as claimed. Further, since Conte et al. discloses that such a release characteristics can be obtained in a predetermined times, it would have been obvious to the one of ordinary skilled in the art to optimize the release characteristic with the experimental manipulations at the time the invention was made. Similarly, with regards to claimed ratios and amounts of various active agents, it is the position of the examiner that these parameters would have been within the purview of a skilled artisan at the time the invention was made to optimize with experimental

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manipulations. . "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

The prior art recognizes the art of formulating anti-Parkinson drugs, such as Carbidopa and Levodopa, in a combined dosage form that provides both immediate and controlled-release characteristics. Hence, the instant invention is deemed unpatentable.

8. Claims 2, 7-15 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Conte et al. (US Patent No. 6,294,200) in view of Vikki et al. (US patent No. 6,500,867).

The teachings of Conte et al. have been discussed above.

Conte et al. do not specifically teach COMT inhibitor such as entacapone in the composition. However, Virkki et al. teaches entacapone in treating Parkinson's disease along with Levodopa and Carbidopa (abstract).

It would have been obvious to the one of ordinary skilled in the art at the time the invention was made to add Entacapone in the composition provided by Conte et al. because Entacapone helps in treating Parkinson's disease. A skilled artisan would thus have been motivated to formulate a composition comprising Carbidopa, Levodopa and Entacapone to treat Parkinson's disease with a reasonable expectation of success. With respect to the various dosage amounts claimed in claims 9-12, it is the position of the examiner that optimization of such a parameter would have been within the purview of a skilled artisan at the time the

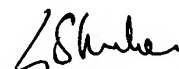
invention was made by doing experimental manipulations. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Snigdha Maewall whose telephone number is (571)-272-6197. The examiner can normally be reached on Monday to Friday; 8:30 a.m. to 5:00 p.m. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Snigdha Maewall

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